

amount varying over time from \$.10 to \$.50 per claim. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5a, 5b, 6.)

4. The Cost of the Drug Product was set at *the lowest of* the drug's Estimated Acquisition Cost ("EAC"), the Federal Allowable Cost (FAC, a/k/a FUL), or (c) the Maximum Allowable Ingredient Cost (MAIC).¹ (Paul Ex. 1 (Gorospe Decl.), at ¶ 5a, 5b.)

5. The Estimated Acquisition Cost for the Subject Drugs was determined at all relevant times at the AWP's reported by First Data Bank ("FDB") less a discount of either 5% (from 1994 through October 2002), 10% (from November 2002 through August 2004), or 17% (August 2004 through December 2004). (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5b, 7.)

B. Mylan Set and Reported AWP's For Its Products Without Regard to The Actual Prices Being Generally and Currently Paid By Providers.

6. Throughout the relevant time period, Mylan set AWP's for its products and reported those prices to pricing compendia, including FDB. (Paul Ex. 2 (11/21/08 Eric Belldina Dep.), at 49:5-22; Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 38:22-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-137:11.)

7. Mylan set the AWP's for its product without even attempting to have those numbers reflect market prices. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 38:22-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-139:18; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

8. When it was the first company to market a particular generic product, Mylan generally set and reported as AWP's for its products a price 10% below the AWP for the corresponding brand product. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 38:19-39:16.)

9. When Mylan launched a product and there was already a competitive generic product on the market, Mylan set its AWP by reference to the competitor's AWP. (Paul Ex. 4

¹ There are no claims paid at MAIC at issue in this case.

(3/28/08 Steve Krinke Dep.), at 137:5-11; Paul Ex. 6 (10/15/08 David Workman Dep.), at 182:22-183:14.)

10. Mylan knew that the generic market was very competitive and that market prices for generic drugs tended to decline significantly after additional participants entered the market. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 153:19-154:21.)

11. Mylan generally did not change its reported AWP in response to changes in transaction prices for its complaint products. (Paul Ex. 7 (9/25/07 Steve Krinke Dep.), at 143:16-146:5; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

12. On occasion, Mylan raised the AWP for a product. (Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 135:16-137:4; Paul Ex. 7 (9/25/07 Steve Krinke Dep.), at 143:16-146:5; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 91:9-92:5.) However, Mylan did not actually sell its product at AWP. (Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

13. Mylan was aware that it was necessary to report AWP to the pricing compendia in order for its products to be reimbursed by third party payers, such as Medi-Cal. (Paul Ex. 9 (10/30/08 Robert Cunard Dep.), at 196:20-197:6; Paul Ex. 2 (11/21/08 Eric Belldina Dep.), at 161:15-23; Paul Ex. 7 (9/25/07 Steve Krinke Dep.), at 87:11-88:1; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 89:1-7, 241:3-15.)

14. FDB published the suggested AWP reported by Mylan as the AWP for Mylan's products. (Paul Ex. 10 (6/26/08 David Workman Dep.), at 35:12-18.)

C. Mylan Was Aware of the Prices Providers Paid For Its Products.

15. Mylan maintained databases through which it regularly tracked the prices at which its products were being sold. (Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 224:8-225:8, 226:3-15, 227:7-11, 229:2-16; Paul Ex. 11 (11/20/08 David Workman Dep.), at 100:19-101:20, 128:2-19, 130:11-131:3, 157:6-23, 158:2-159:10.)

16. For internal business purposes, Mylan calculated accurate estimates of sales prices for its products on a regular basis. (Paul Ex. 11 (11/20/08 David Workman Dep.), at 157:6-23, 158:2-159:10.)

17. Mylan contracted with large retail pharmacy chains for the sale of its products. (Paul Ex. 11 (11/20/08 David Workman Dep.), at 168:12-169:6; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 83:19-84:15.)

18. Mylan did not report its transactional prices, nor any average or compilation of these prices, to the pricing compendia or to Medi-Cal as its products' AWP or otherwise. (Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 37:6-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-139:18.)

19. There was no fixed or predictable relationship between the AWP that Mylan reported to FDB and the prices at which its products were sold to the retail class of trade. (Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20; Paul Ex. 3 (3/25/09 Hal Korman Dep.), at 37:6-39:16; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 136:3-139:18.)

D. Mylan's Knowledge of Medicaid and Medi-Cal Policies

20. Mylan was aware of or on notice of Medicaid and Medi-Cal reimbursement policies in general. (Paul Ex. 12 (6/10/09 Brian Roman Dep.), at 133:22-135:11; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 63:16-65:12, 240:9-242:3, Ex. 12, Ex. 42; Paul Ex. 4 (3/28/08 Steve Krinke Dep.), at 120:1-121:19, Ex. 10.)

21. Mylan was aware of or on notice that Medi-Cal reimbursed providers for pharmaceutical products based, in part, on the reported AWP of the products. (Paul Ex. 9 (10/30/08 Robert Cunard Dep.), at 196:20-197:6; Paul Ex. 8 (11/25/08 Robert Potter Dep.), at 241:3-15; Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 153:22-155:16; Paul Ex. 12 (6/10/09 Brian Roman Dep.), at 141:19-143:11.)

E. Claims Submitted For All of Mylan's Subject Drugs Were Materially False.

22. Plaintiffs' expert, Dr. Leitzinger, used data provided by Mylan to estimate the average prices paid by pharmaceutical wholesaler's customers [i.e., providers] for each of the 217 relevant Mylan NDCs. Dr. Leitzinger did that by calculating the prices that wholesalers paid to Mylan for each NDC and then applying a wholesaler markup to those prices to estimate the total amount that customers paid to wholesalers for each such NDC. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 4.) His methodology is explained more fully at paragraphs 12-20 of his Report, which is attached as Ex. A to his Declaration. The wholesaler markup that Dr. Leitzinger used was based on data contained in the "Industry Profile and Healthcare Factbook," published by the Healthcare Distribution Management Association. That markup ranged over time between 3.7 percent and 5.4 percent. (Paul Ex. 14 (Leitzinger Decl.), Ex. A at ¶ 20, n.20.)

23. Ex. 4 to Dr. Leitzinger's Report shows in column (6) the "spread" (the difference between the average net quarterly prices that he calculated and the reported AWP) for each of the 217 relevant Mylan NDCs on a quarter-by-quarter basis from the first quarter of 1994 through the fourth quarter of 2004. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 5.)

24. For over 93 percent of the Mylan NDC/quarter combinations for which he had complete data, the AWP reported by Mylan exceeded the average net quarterly prices paid by wholesalers' customers by at least 100 percent. For 80 percent of those NDC/quarter combinations, the spread exceeded 300 percent, with some greater than 2,000 percent. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 6.)

25. For purposes of calculating the overpayments made by the State for the 217 relevant Mylan NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Mylan by at least 25 percent. For each

remaining claim, he calculated the difference between the actual ingredient cost reimbursed by the State and an amount 25 percent above the average net price paid by wholesalers to Mylan.

That difference was the overpayment he found. (Paul Ex. 14 (Leitzinger Decl.), at ¶ 7.)

F. Mylan Acted Knowingly in Making the Above False Statements.

26. Mylan has contended that its reported AWP's did not reasonably reflect providers' acquisition costs. (Paul Ex. 13 (Mylan's Objections and Responses to Plaintiff's First Set of Interrogatories), at Interrogatory Number 12, p. 25, "... AWP does not reflect providers' acquisition costs;" Paul Ex. 5 (8/2/07 Brian Roman Dep.), at 128:21-129:20.)

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on November 24, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul
NICHOLAS N. PAUL